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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,875	04/30/2001	Kenneth S. Zuckerman	0152.00393	8728

7590 07/29/2004

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/744,875	<b>Applicant(s)</b> ZUCKERMAN ET AL.	
	<b>Examiner</b> Sean R McGarry	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,8-13,15,16 and 19-57 is/are pending in the application.
- 4a) Of the above claim(s) 1,16,19,30-35 and 40-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-13,20-29 and 36-39 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/8/03</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1635

### **DETAILED ACTION**

Applicant's election with traverse of Group II, claims 8-13, 15, 20-29 and 36-39 in the reply filed on 5/10/04 is acknowledged. The traversal is on the ground(s) that the Pears et al reference does not teach an oligonucleotide wherein a STAT transcription factor of a cells binds to the oligonucleotide. This is not found persuasive because the art does indeed teach such an oligonucleotide as evidenced by the rejections below.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 16, 19, 30-35, and 40-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/10/2004.

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1635

Claim 20 recites "an effective amount of a double-stranded oligonucleotide". The context of the claim does not provide any basis for what might constitute an "effective amount" An effective amount for what, for example? The metes and bounds of the claimed invention is not clear with the use of the terminology.

Claim 20 recites a "pharmaceutically effective carrier" The use of this language is not clear. Is applicants' carrier an effective pharmaceutical, for example?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-13 and 37-39 rejected under 35 U.S.C. 102(b) as being anticipated by Pearse et al [PNAS Vol. 90: 4314-4318, 1993].

Pearse et al disclose composition containing double stranded oligonucleotides that comprise the consensus nucleotide sequence recited in the claims (See Figures 1 and 2, for example). It is noted that the sequences disclosed by Pearse are double stranded and are palindromic. Since the oligonucleotides are palindromic and are double stranded, there are at least two copies of the sequence in the disclosed double stranded oligonucleotides. Since the disclosed sequences of Pearse et al contain the "consensus STAT5 binding site, TTCNNNGAAA" (see page 6 of the instant specification), the oligonucleotides of Pearse et al would, without evidence to the contrary, inherently possess all of the functional properties recited in the claims.

Art Unit: 1635

Claims 8-13 and 37-39 rejected under 35 U.S.C. 102(b) as being anticipated by Wegenka et al [Molecular and Cellular Biology Vol. 13(1):276-288, 1993].

Wegenka et al disclose composition containing double stranded oligonucleotides that comprise the consensus nucleotide sequence recited in the claims (See Figures 1, 6-8, for example). It is noted that the sequences disclosed by Wegenka et al are double stranded and are palindromic. Since the oligonucleotides are palindromic and are double stranded, there are at least two copies of the sequence in the disclosed double stranded oligonucleotides. Since the disclosed sequences of Wegenka et al contain the "consensus STAT5 binding site, TTCNNNGAAA" (see page 6 of the instant specification), the oligonucleotides of Wegenka et al would, without evidence to the contrary, inherently possess all of the functional properties recited in the claims.

Claims 20 and 22-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pearse et al.

Pearse et al disclose composition containing double stranded oligonucleotides that comprise the consensus nucleotide sequence recited in the claims (See Figures 1 and 2, for example). It is noted that the sequences disclosed by Pearse are double stranded and are palindromic. Since the oligonucleotides are palindromic and are

Art Unit: 1635

double stranded, there are at least two copies of the sequence in the disclosed double stranded oligonucleotides. Since the disclosed sequences of Pearse et al contain the "consensus STAT5 binding site, TTCNNNGAAA" (see page 6 of the instant specification), the oligonucleotides of Pearse et al would, without evidence to the contrary, inherently possess all of the functional properties recited in the claims.

Pearse et al do not specifically disclose that the composition/agent contains a "pharmaceutically effective carrier", however it is assumed that the oligonucleotide were, when synthesized, kept in a container with a sterile buffer solution as this was standard practice in the art at the time of invention.

Claims 20 and 22-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wenenka et al.

Wegenka et al disclose composition containing double stranded oligonucleotides that comprise the consensus nucleotide sequence recited in the claims (See Figures 1, 6-8, for example). It is noted that the sequences disclosed by Wegenka et al are double stranded and are palindromic. Since the oligonucleotides are palindromic and are double stranded, there are at least two copies of the sequence in the disclosed double stranded oligonucleotides. Since the disclosed sequences of Wegenka et al contain the "consensus STAT5 binding site, TTCNNNGAAA" (see page 6 of the instant specification), the oligonucleotides of Wegenka et al would, without evidence to the contrary, inherently possess all of the functional properties recited in the claims.

Art Unit: 1635

Wegenka et al do not specifically disclose that the composition/agent contains a "pharmaceutically effective carrier", however it is assumed that the oligonucleotide were, when synthesized, kept in a container with a sterile buffer solution as this was standard practice in the art at the time of invention.

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

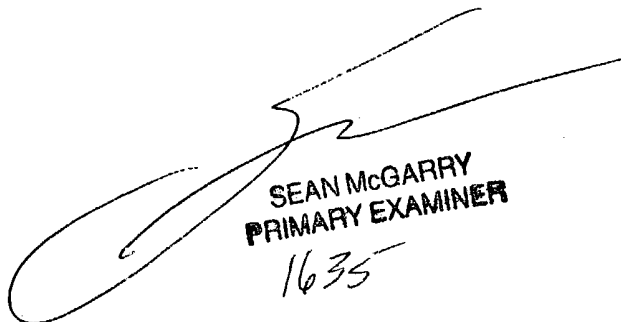
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SRM



SEAN MCGARRY  
PRIMARY EXAMINER  
1635